REMARKS

The Office Action of March 2, 2009, has been received and reviewed.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 are currently pending and under consideration in the above-referenced application. Each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 has been rejected.

Reconsideration of the above-referenced application is respectfully requested.

Claim Objections

The Office has objected to claims 18, 59, 60, 62, 66, and 67 under 37 C.F.R. § 1.75(c) for failing to further limit a claim from which they depend. Claims 18, 59, 60, 62, 66, and 67 have been amended to overcome the objection.

The Office has objected to claims 79 and 80 for an informality: "red rice yeast extract" should be "red yeast rice extract." Appropriate corrections have been made.

Withdrawal of the objections to claims 18, 59, 60, 62, 66, 67, 79, and 80 is respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 stand rejected for allegedly failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Specifically, the Office has objected to use of the terms "vitamin-like substance" and "herb or plant extract" in the claims.

"[T]here is no *in haec verba* requirement..." M.P.E.P. § 2163. In addition to providing an express basis for newly added claim limitations, the specification may also provide an implicit or inherent basis for such limitations. *Id.*

The term "vitamin-like substance" is a term of art. As evidenced by http://www.britannica.com/EBchecked/topic/630930/vitamin/242138/Vitamin-like-substances, from the online version of the Encyclopedia Brittanica, a "vitamin-like substance" includes "a number of organic compounds that, although related to the vitamins in activity, cannot be defined as true vitamins..." The as-filed specification discloses examples of vitamin-like substances

(including, but not limited to, coenzyme Q_{10}, which is characterized by www.wikipedia.org as a vitamin-like substance) that cannot be defined as true vitamins. As such, the as-filed specification provides a written description that adequately supports the recitation of "vitamin-like substances" in independent claims 1, 50, 68, 79, and 80.

Likewise, it is respectfully submitted that one of ordinary skill in the art would readily recognize an herb extract or a plant extract. Among the examples of herb and plant extracts disclosed by the as-filed specification are: butcher's broom (identified as a "root" by the as-filed specification); Ginkgo biloba (identified as a "leaf" by the as-filed specification); hawthorne (identified as including portions of a "flower" and a "leaf" by the as-filed specification); garlic (identified as including a "deodorized clove" by the as-filed specification); reservatrol (identified by the as-filed specification as coming from *Polygonum cuspidatum*, a well known herb); and ginger oil (ginger is a well known root). Thus, the as-filed specification provides an adequate written description for the recitation of the "herb or plant extract" recited by independent claims 1, 50, 68, 79, and 80.

Claims 4-8, 11, 12, 14-16, and 18 are allowable, among other reasons, for depending from independent claim 1, which is allowable.

Each of claims 53-57 and 59-71 is allowable, among other reasons, for depending from independent claim 50, which is allowable.

Neither independent claim 72 nor any of its dependent claims includes either of these recitations. Therefore, the inclusion of claims 72-78 in the 35 U.S.C. § 112, first paragraph, written description rejection is inappropriate.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 were also rejected under the written description requirement of the first paragraph of 35 U.S.C. § 112 on the basis that the as-filed specification purportedly fails to provide "an adequate description for the entire scope" of a "low density lipoprotein (LDL) receptor-binding component," a "blood cholesterol reduction component," a "blood cholesterol reducing element," a "blood flow-enhancing component," or a "fat oxidation prevention element."

Notably, the as-filed specification broadly identifies each of these elements in either the same manner or a manner similar to that quoted above, and discloses specific embodiments of each of these elements. *See, e.g.,* paragraphs **[0013]**, **[0017]**, and **[0023]** through **[0027]**.

"There is a strong presumption that an adequate written description is present in the specification as filed..." M.P.E.P. § 2163. "[T]he examiner has the initial burden of presenting evidence or reasoning to explain why person skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." M.P.E.P. § 2163.04.

The Office has merely asserted that "[t]he claims are essentially of limitless breadth" and that it would be far too difficult for one of ordinary skill in the art to distinguish between substances that are within the scope of a particular element and substances that are not within the scope of that element. The Office has ignored the fact that each of the elements at issue, in name, has specific limitations that narrow the number of possible embodiments to a group that may be readily predicted by one of ordinary skill in the art. The Office has not provided any evidence or logical reason has to why one of ordinary skill in the art wouldn't understand the scope and meaning, or to identify substances that fall within the groupings, of any of a "low density lipoprotein (LDL) receptor-binding component," a "blood cholesterol reduction component," a "blood cholesterol reducing element," a "blood flow-enhancing component," or a "fat oxidation prevention element."

Thus, the Office has not shown that the as-filed specification lacks an adequate written description for any of these elements, as would be required for the Office to maintain its 35 U.S.C. § 112, first paragraph, adequate written description rejections of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80.

Notably, claims 72, 73, 79, and 80 do not include any of the recitations at issue in this particular rejection. Thus, the inclusion of these claims in this rejection is improper.

Withdrawal of the 35 U.S.C. § 112, first paragraph, rejections of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 is respectfully requested, as is the allowance of each of these claims.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 stand rejected under 35 U.S.C. § 103(a).

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also "be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Vester, Kirkpatrick, Campbell, Williamson, Goodman, Rath, Tentolouris, Kemper and Szapary

Claims 1, 7, 8, 11, 12, 14-16, 18, 50, 56, 57, 59-67, and 72-80 have been rejected under 35 U.S.C. § 103(a) for reciting subject matter that is allegedly unpatentable over the teachings of U.S. Patent 6,203,818 to Vester (hereinafter "Vester"), in view of teachings from Kirkpatrick, *"Properties and Activities of Transfer Factor,"* J. Allergy & Clin. Immunol., 55(6):411-421 (1975) (Abstract) (hereinafter "Kirkpatrick"), Campbell et al., *"Chlamydia pneumonia and Cardiovascular Disease"*, Emerging Infectious Diseases, 4(4):571-579 (1998) (hereinafter "Campbell"); Williamson et al., "*Herbal therapies: The facts and the fiction*," Drug Topics, pp. 78-87, (hereinafter "Williamson"); U.S. Patent 6,022,910 to Goodman (hereinafter "Goodman"), U.S. Patent 6,506,413 to Rath et al. (hereinafter "Rath"), Tentolouris et al., *"L-Arginine in*

coronary atherosclerosis," Int'l J. Cardiol., 75:123-128 (2000) (hereinafter "Tentolouris"); Kemper, Ginger (Zingiber officinale), Longwood Herbal Task Force: http://www.mcp.edu/herbal/default.html 1999, pp. 1-18 (hereinafter "Kemper"); and Szapary et al., Alternative Medicine in Cardiovascular Disease: "*More Questions than Answers*", ACC Current Journal Rev., pp. 104-108 (hereinafter "Szapary").

It is respectfully submitted that the Office has not articulated any specific reason for one of ordinary skill in the art to have combined teachings from Vester, Kirkpatrick, Campbell, Williamson, Goodman, Rath, Tentolouris, Kemper and Szapary. In fact, a review of the remarks provided in the Office Action of March 2, 2009, indicates that only reason for combining the teachings of these references was to improperly rely upon hindsight to reconstruct the compositions recited by the rejected claims.

Of peculiar interest is the Office's reliance upon teachings from Szapary, which teaches a number of additional approaches, including the administration of fish oils and the use of chelation therapy (*e.g.,* use of ethylenediamine tetraacetic acid – EDTA), to treat cardiovascular disease. Notably, independent claims 1, 50, 68, 79, and 80 are drawn to nutritional supplements that "consist of" certain ingredients. If one of ordinary skill in the art would have been motivated to combine elements from a diverse grouping of substances that might treat cardiovascular disease into a nutritional supplement, then rely upon Szapary's teaching that the inclusion of red yeast rice would further improve the nutritional supplement, then Szapary would have also motivated one of ordinary skill in the art to have included fish oils in the nutritional supplement.

Due to the "consisting of" language in independent claims 1, 50, 68, 79, or 80, a nutritional supplement that includes fish oils would not render the nutritional supplements of any of these claims (or of any of their dependent claims) obvious to one of ordinary skill in the art. Thus, in order to craft its 35 U.S.C. § 103(a) rejections, the Office had to ignore Szapary's teachings that fish oils are useful for treating cardiovascular disease, the Office has demonstrated it was relying completely and improperly upon hindsight to reconstruct the claimed nutritional supplements.

Additionally, although independent claims 79 and 80 are limited to nutritional supplements that include defined lists of ingredients, the Office has relied upon a number of references that teach or suggest the inclusion of additional ingredients. For example, according to Vester, the use of quercetin in conjunction with folic acid is particularly preferred. *See, e.g.,* col. 2, lines 7-8; col. 3, lines 6-7. Quercetin may not be a component of the nutritional supplement of independent claim 79 or of the nutritional supplement of independent claim 80. According to Goodman, the inclusion pharmacologically active agents for preventing or treating restinosis or for countering or inhibiting side effects, allergies, or the like are highly desirable. Col. 8, lines 28-37. Szapary teaches a number of ingredients may not be included in the nutritional supplement of independent claim 79 or in the nutritional supplement of independent claim 80. Specifically, Szapary teaches that horse chestnut seed extract, artichoke leaf extract, fish oils, and plant sterols and stanols are useful in combating cardiovascular disease.

As for the subject matter to which independent claim 72 and its dependent claims 73-78 are drawn, none of Vester, Kirkpatrick, Campbell, Williamson, Goodman, Rath, Tentolouris, Kemper and Szapary, taken alone or in any combination, teaches or suggests a composition that includes a preparation including transfer factor and vitamin C ***in the same amounts***. The Office has not articulated any reasoning to support its rejection of independent claim 72 or its dependent claims 73-78, let alone any reason for one of ordinary skill in the art to have combined teachings from Vester, Kirkpatrick, Campbell, Williamson, Goodman, Rath, Tentolouris, Kemper, and Szapary to develop a composition that includes transfer factor and vitamin C in the same amounts.

Moreover, while Campbell teaches that *Chlamydia pneumonia* causes acute respiratory disease, none of the references that have been relied upon in rejecting claims 1, 7, 8, 11, 12, 14-16, 18, 50, 56, 57, and 59-67 teaches or suggests a composition that includes transfer factor that is specific for *Chlamydia pneumoniae,* or for any of herpes simplex virus type I, herpes simplex virus type II, cytomegalovirus, or *Heliobacter pylori,* as is required of the compositions recited by independent claim 1 and independent claim 50. In this regard, the teachings of Kirkpatrick are limited to a broad discussion of transfer factor without any teaching or suggestion

regarding specificity, or even the possibility that transfer factors may be generated against any of the listed pathogens.

Therefore, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness against any of claims 1, 7, 8, 11, 12, 14-16, 18, 50, 56, 57, 59-67, or 72-80, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

Vester, Kirkpatrick, Campbell, Williamson, Goodman, Rath, Tentolouris and Tokoro

Claims 1, 4-6, 53-55, and 68-71 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the subject matter taught by Vester, in view of teachings from Kirkpatrick, Campbell, Williamson, Goodman, Rath and Tentolouris and, further, in view of the teachings of U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro").

As demonstrated above, the Office's reliance upon the diverse teachings of Vester, Kirkpatrick, Campbell, Williamson, Goodman, Rath, and Tentolouris is nothing more than an impermissible hindsight reconstruction. Even though the Office does not rely upon teachings from Szapary in this particular rejection, its actions are already apparent. Tokoro provides no teaching or suggestion that remedies the Office's improper reliance upon hindsight.

Moreover, as has already been established, Tokoro does not provide any teaching or suggestion of a composition that includes transfer factor. Rather, the teachings of Tokoro are limited to a transfer factor-like substance that the art indicates is something other than transfer factor.

In any event, none of the cited references teaches or suggests a nutritional supplement that includes transfer factor that is specific for *Chlamydia pneumoniae,* or for any of herpes simplex virus type I, herpes simplex virus type II, cytomegalovirus, or *Heliobacter pylori,* as is required of the nutritional supplements of independent claims 1, 50, and 68.

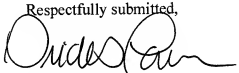
Therefore, the Office has not established a *prima facie* case of obviousness against independent claim 1, independent claim 50, independent claim 68, or any of their dependent claims.

Therefore, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 is respectfully requested, as is the allowance of each of these claims.

CONCLUSION

It is respectfully submitted that each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-80 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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